American Medical Women's Association

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

Comments of Members of the Patient, Consumer, and Public Health Coalition
on Proposed Order that splits cardiovascular device into two classifications

Proposed Order: "Cardiovascular Devices; Reclassification of Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass; Effective Date of Requirement for Premarket Approval for Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Temporary Ventricular Support."
[Docket No. FDA-2013-N-1518]

As members of the Patient, Consumer, and Public Health Coalition, we strongly support the FDA's proposed order for Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Temporary Ventricular Support devices to remain in Class III with Premarket Approval applications (PMA) required. The evidence of safety and effectiveness for these indications has not been established, and the benefit/risk profile for these devices is "unknown."[1]

However, we strongly oppose the FDA's proposed order to down-classify Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass from Class III to Class II with special controls.

A major problem with this proposed order is that it splits the device into two classifications (Class III and Class II). A down classification from Class III to Class II (and 510(k) clearance) would not require a sponsor to prove that their product is safe or effective. Even if the device were cleared by the 510(k) process for one particular indication, it could easily be used off-label for treatments that require a PMA. In other words, down-classification for any indication would create an enormous and dangerous loophole that would allow manufacturers to avoid the more rigorous PMA review process.

FDA specifies that life-supporting devices should be considered Class III (high-risk devices), and require the more rigorous PMA review, unless special controls are adequate to ensure that the products are safe and effective, making clinical trials, inspections, and other provisions of the PMA process unnecessary.

FDA has noted seven significant risks associated with these devices, including risks that "can result in debilitating or fatal complications such as stroke, peripheral emboli, or death."[1] To mitigate the risk of stroke or death, FDA is proposing special controls but these controls rely on non-clinical testing and non-clinical performance evaluation. These special controls are inadequate to provide reasonable assurance of safety and effectiveness for these complex, life-supporting devices.

The FDA justifies down-classifying the device by stating that "FDA has been reviewing these devices for many years and their risks are well known." But the FDA's Manufacturer and User Facility Device Experience (MAUDE) is a passive adverse reporting system and is widely acknowledged to undercount adverse events. This undercounting of adverse events undermines the argument that "risks are well known." Even though it undercounts, the MAUDE database shows 729 adverse events associated with the Nonroller-Type Cardiopulmonary Bypass Blood Pumps (Product Code KFM) including 73 deaths and 96 injuries.

A review of the FDA's Total Product Life Cycle (TPLC) Web page for the device shows 500 device problems including pumping malfunctions (stoppage or failure to pump). The TPLC for Product Code KFM also showed nine recalls from 2007 – 2012 (one Class I and eight Class II recalls).

Relying on special controls with the 510(k) review process will not provide four essential safeguards that Class III devices receive when they are reviewed under the PMA process:

1. Proof of safety and efficacy based on short-term clinical trials.
2. FDA's authority to require post-market, long-term clinical trial safety data as a condition of approval.
3. FDA's authority to inspect the manufacturing facility prior to approval.
4. FDA authority to rescind approval if the device is later found to be unsafe.

In addition, the FDA proposal suggests that the safety of Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass that are currently on the market is the only concern. However, the down-classification of these devices means that companies manufacturing new models with unique characteristics in the future would not be required to prove that their products are safe or effective. The companies would only need to prove that their products are substantially equivalent to other Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass already on the market, and would not require scientific evidence to ensure equivalent safety or efficacy.

In conclusion, the Institute of Medicine report on the 510(k) process for Class II devices pointed out the criteria that the FDA uses to determine equivalence is not sufficient to ensure that the products are safe or effective. Clinical trials are needed to ensure the safety and efficacy of

high-risk, life-sustaining devices. The FDA's TPLC Web page shows serious problems related to these devices and the MAUDE database has recorded deaths and injuries associated with them, which one has to assume is the tip of the iceberg in a voluntary reporting system.

For those reasons, the FDA should not down-classify the Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass. Instead, Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass should remain Class III devices for all indications and all new Nonroller-Type Cardiopulmonary Bypass Blood Pumps should require PMAs. Clinical trials, inspections, and other safeguards of the PMA process are essential to protect the health of patients.

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[1] Federal Register (January 7, 2014). Food and Drug Administration proposed order for cardiovascular devices. Docket No. FDA-2013-N-1518.